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DORSEY & WHITNEY, LLP			PAPAPIETRO, JACQUELINE M	
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Please find below and/or attached an Office communication concerning this application or proceeding.

3) Information Disclosure Statement(s) (PTO/SB/08)

Paper No(s)/Mail Date <u>05/11/2004</u>.

Notice of Informal Patent Application

6) Other: \_

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#### **DETAILED ACTION**

### **Drawings**

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following figures not mentioned in the brief description of the drawings: Figures 15A-18. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

#### Claim Objections

Claim 4 is objected to because of the following informalities: line 2 recites, "electrode strand is comprised of, at least partially, of material..." which is grammatically incorrect due to an extra "of." Appropriate correction is required.

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Claim 14 is objected to because of the following informalities: line 1 recites, "wherein at least partial curve defines..." and omits an article before "at least partial curve." Appropriate correction is required.

Claim 18 is objected to because of the following informalities: the claim recites, "the generally continuously exposed segments." There is proper antecedent basis for "the generally exposed segment", but not for the plural "segments," as it is written in the claim. Appropriate correction is required.

### Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 15-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 15 recites "wherein at least one electrode strand" in line 1 and then recites "the electrode strand" in line 2 of claim 15, "the at least one electrode strand" in claims 16-17, and "the at least one strand" in claim 18. Because line 1 does not recite "wherein the at least one electrode strand," it is unclear to what the future recitations of "the electrode strand" refer (the at least one electrode strand of claim 2 or possibly another at least one electrode strand as recited in claim 15).

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### Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Kordis (PN 5499981).

Regarding claim 1, Kordis discloses an ablation catheter (10) comprising: a tubular body (98) having a distal end region (Fig 38), the tubular body defining at least a partial curve along the distal end region of the tubular body (Fig 38), the partial curve being adapted to change curvature (column 8 lines 52-53 and Fig 38); and at least one electrode (96) arranged along the at least partial curve (Fig 38), the at least one electrode being adapted to change curvature along with the at least partial curve along the distal end region of the tubular body (Fig 38).

Regarding claim 2, Kordis discloses the ablation catheter of claim 1 wherein the at least one electrode comprises at least one electrode strand (Fig 41) arranged in a flexible configuration (column 6 lines 3-4 and column 12 lines 54-56).

Regarding claim 3, Kordis discloses the ablation catheter of claim 2 wherein the at least one electrode comprises at least one flexible and resilient (column 6 lines 9-11) electrode strand (elements 22, 92, and 96).

Regarding claim 4, Kordis discloses the ablation catheter of claim 3 wherein the at least one flexible and resilient electrode strand is comprised, at least partially, of

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material selected from the group consisting of platinum (column 12 line 20), gold, stainless steel (column 6 line 64), and composite of conductive polymer metal.

Regarding claim 5, Kordis discloses the ablation catheter of claim 2 wherein the at least one electrode strand defines a saw tooth pattern (Fig 35).

Regarding claim 6, Kordis discloses the ablation catheter of claim 2 wherein the at least partial curve defines an outside radius (inherent with a curved tube), and wherein the at least one electrode strand defines a first end region (E1) and a second end region (E8), and wherein the first end region is coupled with a point along the outside radius of the at least partial curve and wherein the second end region is coupled with a second point along the outside radius of the at least partial curve along the distal end region of the tubular body (Figs 52, 41, and 38).

Regarding claim 7, Kordis discloses the ablation catheter of claim 2 wherein the at least one electrode strand (22, 92, and 96) further defines an elastically deformable strand (column 6 lines 9-10 and column 12 lines 54-56).

Regarding claim 8, Kordis discloses the ablation catheter of claim 7 wherein the at least one elastically deformable strand (22, 92, and 96) is biasedly coupled with the at least partial curve along the distal end region of the tubular body (Fig 41, element 22 provides the curvature).

Regarding claim 9, Kordis discloses the ablation catheter of claim 8 wherein the biased connection of the at least one elastically deformable strand (22, 92, and 96) is biased to change the curvature of the at least partial curve along the distal end region of the tubular body (Figs 1A and 2).

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Regarding claim 10, Kordis discloses the ablation catheter of claim 1 wherein the at least partial curve along the distal end region of the tubular body defines a closed loop (Fig 2, the loop in a closed configuration), as broadly claimed.

Regarding claim 11, Kordis discloses the ablation catheter of claim 1 wherein the at least partial curve along the distal end region of the tubular body defines an open loop (Fig 1A, the loop in an open configuration), as broadly claimed.

Regarding claim 12, Kordis discloses the ablation catheter of claim 2 wherein the at least one electrode includes at least one electrode strand interlaced along the at least partial curve along the distal end region of the tubular body (Fig 41).

Regarding claim 13, Kordis discloses the ablation catheter of claim 12 wherein the at least partial curve defines an outside surface, and wherein the at least one electrode strand is interlaced along the outside surface (Fig 41).

Regarding claim 14, Kordis discloses the ablation catheter of claim 12 wherein the at least partial curve defines an inside surface, and wherein the at least one electrode strand is interlaced along the inside surface (Fig 38 at the base of the loop structure).

Regarding claim 15, Kordis discloses the ablation catheter of claim 13 wherein the at least one electrode strand is interlaced along the outside circumference such that the electrode strand is intermittently exposed along the outside circumference (Figs 38-41).

Regarding claim 16, Kordis discloses the ablation catheter of claim 15 wherein: the at least one electrode strand defines a first length of the at least one strand (E1-E4),

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the first length defining intermittently exposed sections of the at least one electrode strand (Fig 52); and the at least one electrode strand further defines a second length of the at least one strand (E5-E8), the second length defining intermittently exposed sections of the at least one electrode strand (Fig 52).

Regarding claim 17, Kordis discloses the ablation catheter of claim 16 wherein the first length of the at least one strand and the second length of the at least one strand cooperate to define a generally continuously exposed segment of the at least one strand (E1-E8, Fig 52).

Regarding claim 18, Kordis discloses the ablation catheter of claim 17 wherein the generally continuously exposed segment of the at least one strand is coupled (28) with a power supply and adapted to be energized thereby during an ablation procedure (column 1 lines 9-11). The catheter inherently must be coupled with a power supply in order to function as an ablation tool.

Regarding claim 19, Kordis discloses an ablation catheter comprising: a tubular shaft (98) defining a distal end region (Fig 38), the tubular shaft further defining at least a partial curve along the distal end region (Fig 38); and flexible electrode means for conveying ablation energy to a target tissue (96 and 92), the flexible electrode means arranged along the at least partial curve along the distal end region of the tubular shaft (Fig 38).

Regarding claim 20, Kordis discloses the ablation catheter of claim 19 wherein the means for conveying ablation energy to a target tissue comprises at least one electrode strand (22, 92, and 96) arranged in a flexible configuration (column 6 lines 3-4

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and column 12 lines 54-56) along some portion of the at least partial curve along the distal end region of the tubular shaft (Fig 38).

## Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 17-18 are rejected under 35 U.S.C. 102(b) as anticipated by Kordis (as applied above) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kordis.

Regarding claim 17, Kordis discloses the ablation catheter of claim 16, as described above, wherein the first length of the at least one strand and the second length of the at least one strand cooperate to define a generally continuously exposed segment of the at least one strand (as described above). Furthermore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to

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have modified Kordis by increasing the length of the electrodes E1-E8 and decreasing the space between these electrodes, thereby creating an even more generally continuously exposed segment, in order to expose a larger area of the electrodes and ablate more tissue at one time.

Regarding claim 18, Kordis discloses the ablation catheter of claim 17 wherein the generally continuously exposed segment of the at least one strand is coupled with a power supply and adapted to be energized thereby during an ablation procedure (as described above). Furthermore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have coupled the electrode strand with a power supply in order to perform the desired function of the apparatus and ablate tissue.

#### Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Swanson et al (Patent Number 6171306 B1).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacqueline Papapietro whose telephone number is (571) 272-1546. The examiner can normally be reached on M-F 8am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jacqueline Papapietro
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MICHAEL PEFFLEY
PRIMARY EXAMINER